

PATENT COOPERATION TREATY


PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

RECD 10 JUL 2006

Applicant's or agent's file reference 2003023-WO		FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/DK2005/000141		International filing date (day/month/year) 01.03.2005		Priority date (day/month/year) 01.03.2004
International Patent Classification (IPC) or national classification and IPC INV. A61F5/445 A61F5/441 A61F5/448				
Applicant COLOPLAST A/S et Al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 10 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 28.12.2005			Date of completion of this report 06.07.2006	
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016			Authorized officer Germano, A Telephone No. +31 70 340-4202	



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Box No. I Basis of the report

1. With regard to the **language**, this report is based on
- ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-18 as originally filed

Claims, Numbers

1-31 as originally filed

Drawings, Sheets

1/15-15/15 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees, the applicant has, within the applicable time limit:
- ☐ restricted the claims.
 - ☐ paid additional fees.
 - ☐ paid additional fees under protest and, where applicable, the protest fee.
 - ☐ paid additional fees under protest but the applicable protest fee was not paid.
 - ☐ neither restricted the claims nor paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
- ☐ complied with.
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
 - ☐ the parts relating to claims Nos. .

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-13,15-24
	No: Claims	14,25-31
Inventive step (IS)	Yes: Claims	1-13
	No: Claims	14-31
Industrial applicability (IA)	Yes: Claims	1-31
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item IV

Lack of unity of invention

1. The application refers to four different inventions and therefore fails to meet the requirements of Rule 13.1 PCT

The four different inventions referred to in the application are:

- a) a disposable inner bag liner according to claims 1 to 13,
- b) a disposable inner bag liner according to claims 14 to 24,
- c) an ostomy appliance according to claims 25 to 27, and
- d) a method of applying an inner bag liner to a receiving member according to claims 28 to 31.

- 1.1 According to Rule 13.1 PCT, an International Application may relate only to one invention, or to a group of inventions (generally defined in different independent claims) so linked as to form a single general inventive concept.

In the second case, the concept linking the inventions finds expression in the different independent claims according to the different inventions in terms of the same or corresponding technical special features, wherein the expression "technical special features" means the features which involve an inventive contribution over the prior art, see Rule 13.2 PCT.

- 1.2 In the present case the same or corresponding technical feature of claims 1, 14 and 25 are:

"a disposable inner bag liner for an ostomy appliance, the inner bag liner being provided with a first surface provided with an adhesive and a release liner, and a second surface being adapted to be attached to at least a part of an outer receiving member"

These features however are known from the prior art, see EP-A-320 895, US-A-5 591 144 or DE-A-19 519 069, and they are thus not only not inventive but even not

new. All of the other features of said claims are different and directed to different purposes. Therefore there is no common inventive concept linking the inventions according to claims 1, 14 and 25.

- 1.3 Claim 28 is not clear, see Item VIII. Insofar as the claim may be understood, it appears that its subject-matter is not linked by an inventive concept with the subject-matter of claim 1 and 14. In particular the only corresponding feature between said claims is the inner bag liner, the providing of which is foreseen in claim 28. However, this inner bag liner and its providing are well known, see Item V below.

Therefore no inventive concept links the inventions according to claims 1, 14, 25 and 28 and the application, being directed to four different inventions, does not meet the requirements of Rule 13.1 PCT.

2. However, in view of Rule 68.1, no extra fees are requested for extending the substantive examination to the four groups of claims cited above.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

3. Claim 1 is not clear, see Item VIII. In order to clarify its matter for the purpose of the substantive examination, it has been considered to be directed to a combination of a disposable inner bag liner and a receiving member, see point 15 of Item VIII.

- 3.1 The document DE-A-19 519 069, see fig. 1 and col. 2, line 53 to col. 3, line 33 (the signs refer to said document while the wording is that of claim 1) discloses;

"a disposable inner bag liner (8) for an ostomy appliance, the inner bag liner (8) being capable of forming a bag inside an outer receiving member (4), the disposable inner bag liner (8) comprising an open end (9) having an annular first flange (7) comprising:

- a first hole (9) for receiving a stoma, ureter, or catheter for receiving effluents or

- waste products of the body,
 - a first surface being provided with an adhesive and a release liner (see col. 3, lines 3-9),
- the outer receiving member (4) comprising:
- a second hole (5) for receiving a stoma, ureter or catheter for receiving effluents or waste products of the body, and
 - a second flange (6),
- wherein the second flange (6) of the member (4) and the second surface of the liner (8) are adapted to be releasably adhered to each other.

- 3.2 The subject-matter of claim 1 differs thus from this disclosure in that it specifies that the release liner is provided with first alignment means for aligning the first flange in relation to the second flange.

In view of said difference the subject-matter of claim 1 is new and meets the requirements of Art. 33(2) PCT.

- 3.3 The above mentioned feature has the purpose of facilitating the correct positioning of first and second flange. None of the available prior art documents describes this feature for the same purpose.

Therefore claim 1 involves an inventive step and meets the requirements of Art. 33(3) PCT.

- 3.4 The device described in claim 1 is industrially manufacturable. Therefore the requirements of Art. 33(4) PCT are also met.

4. Claims 2-13 refer to further embodiments of the device described in claim 1 and for this reason meet the requirements of Art. 33(2), (3) and (4) as well.

5. Document EP-A-320 896, see figs. 1, 3-7 and col. 7, line 32 to col. 8, line 20 (the signs refer to said document while the wording is that of claim 14) discloses;
"a disposable inner bag liner (1,2) for an ostomy appliance, the inner bag liner (1,2) being provided with a first surface (7) provided with an adhesive (9) and a release

liner (8), and a second surface being adapted to be attached to at least a part of an outer receiving member (see figs. 6, 7),

Claim 14 further specifies that the release liner (8) comprises gripping means.

Although this feature is not expressis verbis described in said document, it has to be considered that it belongs to the normal practice to provide a gripping means to allow the removal of a protective liner. Therefore also this features is considered to be comprised in the disclosure of EP-A-320 896.

In view of the above the subject-matter of claim 14 is not new and the claim does not meet the requirements of Art. 33(2) PCT.

6. Claims 15 to 22 define different possible forms of the gripping means. These forms however are merely choices among well known equivalents of the forms which can be given to the gripping means.

Therefore the subject-matter of said claims is new and meet the requirements of Art. 33(2) PCT, but does not involve an inventive step, contrary to the requirements of Art. 33(3) PCT.

7. The features of claims 23 and 24 refer to well known measures to protect the inner bag liner before use. Although they are not clearly disclosed in the prior art, they belong to the usual practice to protect a bag liner for ostomy appliances.

Therefore the subject-matter of said claims is considered to meet the requirements of novelty of Art. 33(2) PCT, but not the requirements of inventive step of Art. 33(3) PCT.

8. The features of claim 25 and its dependent claims 26 and 27 are disclosed in combination in the above mentioned DE-A-19 519 069.

Therefore the subject-matter of said claims is not new and does not meet the requirements of Art. 33(2) PCT.

9. The same document DE-A-19 519 069 is considered to be detrimental for the novelty

of the method claims 28 to 31: the skilled man, in order to apply the inner bag liner to the receiving member described in said document would necessarily perform the method described in said claims. Therefore the subject-matter of said claims is not new and does not meet the requirements of Art. 33(2) PCT.

Re Item VII

Certain defects in the international application

10. According to the requirements of Rule 6.3(a)(I) and (ii), the independent claims should have been shaped in the two part form.
11. In order to meet the requirements of Rule 6.2(b), the relevant reference signs should have been introduced after the features of the claims.
12. In order to meet the requirements of Rule 5.1(a)(ii), the description should have been augmented by an acknowledgement of the documents disclosing the closest prior art (see Item V above) and a brief résumé of them.
13. In order to comply with the requirements of Rule 5.1(a)(ii) the description should have been amended so as to disclose the invention as claimed.

Re Item VIII

Certain observations on the international application

14. The expressions "adapted to..." used in claims 1 to 5, 7, 8, 14, 25 and 27 merely refer to a use and do not define a technical feature of the invention, as required by Rule 6.3a) the invention. In view of that said claims are not clear and do not meet the requirements of Art. 6 PCT.
15. Claim 1 lacks clarity also in view of the fact that, according to its wording, it is directed only to a disposable inner bag liner, but is characterized by features of the outer receiving member into which the liner should be disposed, and of features of

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the combination of this member with the liner, the outer receiving member being not part of the claimed matter. According to Rule 6.3a), the definition of the matter for which the protection is sought must be in terms of technical features of the matter itself.

Attempting to define the invention in terms of features of matter which does not belong to the invention involves ambiguity and lack of clarity.

In view of the above mentioned inconsistency it is not possible to understand for which matter the protection is sought. Therefore claim 1 does not meet also for this reason the requirements of Art. 6 PCT.

The present report has been draft considering that the subject-matter of claim 1 comprises in combination the disposable inner bag liner **and** the outer receiving member.

If the subject-matter of the claim were considered to be limited to the disposable inner bag only, then it could not be considered new in view of the disclosure of DE-A-19 519 069

16. Claim 28 refers to "an inner bag liner" according to any of claims 1-24 and to "a receiving member" according to the same claims. However, claims 1 to 13 refer to a combination of an inner bag liner with a receiving member, while claims 14-24 refer to a bag liner only, which is different from a bag liner described in claim 1. In view of said inconsistencies claim 28 and its dependent claims are not clear and do not meet the requirements of Art. 6 PCT.